DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 21, 2014

Home Skinovations Ltd.
Ms. Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata'as Street, Suite 102
Kfar Saba 44425, Israel

Re: K141242
Trade/Device Name: Home Skinovations Glide Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHT, ONF
Dated: August 19, 2014
Received: September 3, 2014

Dear Ms. Stein:

This letter corrects our substantially equivalent letter of December 17, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141242

Device Name
Glide Device

Indications for Use *(Describe)*
The Glide™ device is an over the counter device intended for the removal of unwanted hair. The Glide™ device is also intended for permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## Section 5:

# 510(k) Summary

## 510(K) SUMMARY

# HOME SKINOVATIONS GLIDE DEVICE

**510(k) Number K141242**

**Applicant Name:**


Company Name: Home Skinovations Ltd.
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E-mail: ahava@asteinrac.com


**Contact Person:**


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**Date Prepared:** May 8, 2014

**Trade Name:** Glide Device

**Classification Name:** CFR Classification section 878.4810; (Primary Product Code OHT, Secondary Product Code ONF)

**Classification:** Class II Medical Device

**Predicate Device:**

The Glide device is substantially equivalent to the following predicate devices.

| Manufacturer | Device | 510(k) No. |
|---|---|---|
| **Home Skinovations Ltd.** | Glide | K131870 |

**Device Description:**

The Glide device is a pulsed light hair removal device. Light-based hair removal is based on the theory of selective photothermolysis in which optical energy is used to disable hair growth. The Glide device is composed of a hand held applicator. The device contains 6 LEDs indicating 5 different energy levels and other device functions. The spot size in the Glide device is $2.7cm^2$. The device contains a lamp, a temperature sensor, a skin proximity sensor and a skin color sensor to detect appropriate skin tones. The skin sensor scans darker skin tones and will not pulse if the skin tone is not suitable for treatment.

**Intended Use/Indication for Use:**

The Glide™ device is an over the counter device intended for the removal of unwanted hair. The Glide™ device is also intended for permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

**Performance Standards:**

No new standards have been cited for this submission.

**Non-Clinical (Bench) Performance Data:**

The Glide device is identical in all details to the Glide device cleared under K131870. No new non-clinical performance data is reported in this submission.

**Clinical Performance Data:**

The Glide device was evaluated in a prospective clinical study for the intended use of hair removal. The study evaluated hair removal from facial skin (below cheekbone line), for follow up durations of 1 and 3 months after completion of the last treatment. No adverse events related to the treatment were reported.

**Substantial Equivalence:**

The Glide device is identical to the Glide device previously cleared under K131870. The indications for use and technological characteristics of the Glide device are substantially equivalent to the indications for use and technological characteristics of the previously cleared Glide device.

Consequently, it can be concluded that the Glide device is substantially equivalent to the predicate Glide device, cleared under 510(k) K131870, and therefore, may be legally marketed in the USA.

**Conclusions:**

Based on the performance testing and comparison to predicate devices, the Glide device is substantially equivalent to the previously cleared Glide predicate device.